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03-20-03

PATENT

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellant : Alan R. Hirsch  
Serial No. : 09/211,507  
Filing Date : December 14, 1998  
For : USE OF ODORANTS TO ALTER BLOOD FLOW TO THE VAGINA  
Group Art Unit: 1651  
Examiner : C. Tate  
Docket No. : INS-31061  
Confirmation No.: 9827

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**CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10**

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**37 CFR 1.8(a)**

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Date: 3-13-03

Assistant Commissioner for Patents  
Washington, D.C. 20231

**APPELLANT'S REPLY BRIEF**

Sir:

This is in response to the Examiner's Answer mailed January 15, 2003, in the above-identified application.

**(11) Response to Argument.**

First of all, throughout the Examiner's Answer, the Examiner repeatedly states that the "Appellant argues that the Examiner asserts..." To clarify, Appellant is not arguing that the Examiner is asserting various positions. Rather, Appellant is restating the Examiner's arguments from the final Office Action.

In addition, in the Examiner's Response at page 7 (first sentence of 2<sup>nd</sup> parag.), the Examiner mistakenly states "and the pending claims are directed to an *article...*" (emphasis added). The pending claims are directed to methods of administering an odorant mixture to alter blood flow to the vagina of a female individual.

The Examiner has not fully considered nor adequately addressed Appellant's arguments. The Examiner has provided no good basis for his position that the claims are not fully enabled and utilize indefinite language.

**A. Rejection under 35 U.S.C. § 112(1).**

The Examiner raises a new issue in his Response at page 8. The Examiner now argues that the odorants "do not even define the amounts and/or ratios of one odorant to another" and maintains that the "claims encompass the *in vivo* use of a mixture of any and all percentages and/or ratios of one recited odorant to the other..." The Examiner asserts that this would have "a dramatic impact...with respect to the overall odor emitted from each odorant mixture upon *in vivo* administration, including in terms of determining the actual odorant encompassed by any one of the various mixtures of odorants instantly claimed."

The Examiner ignores the teachings by Appellant as to the character of the recited odorant mixtures required to achieve the claimed effect, and the high level of skill that exists in the odorant art area. Appellant has provided supporting arguments and evidence of the high level of skill in the odorant arts and the techniques routinely utilized in determining and fabricating various odorant compositions. Appellant has provided a sufficient description in the specification to enable a skilled artworker in the odorant arts to obtain and utilize odorant mixtures other than the exemplary odorant mixtures used by Appellant in his experimental example to demonstrate the effectiveness of his inventive method.

The percentage or ratio of the odorants within the recited mixture is not critical. What is required according to Appellant's invention is that the recited mixture comprise an odorant having the stated odor (aroma) (i.e., chocolate, licorice, cucumber, etc.) and that the odorant mixture *alters blood flow to the vagina*. It is implicit that the odorant mixture is not within the scope of the claims unless the odorant mixture comprises the recited odorants and achieves the recited effect.

Each of the odorants of a particular mixture possesses a distinct and characteristic aroma or odor that defines the particular odorant. It is well within the skill in the art to combine the appropriate odorant to provide the recited mixture without undue experimentation.

Indeed, in an art having a high level of skill — as evidenced by the Doty publication cited by the Examiner (Appeal Brief at Tab C), and the additional documentation provided by Appellant (Appeal Brief at Tabs D-G) — a skilled artworker in the odorant arts would readily ascertain whether a substance had a chocolate aroma, a licorice aroma, a banana nut bread aroma, a cucumber aroma, a lavender aroma, or a baby powder aroma — regardless of whether the substance was the commercial source disclosed, or another synthetic or natural source — and fabricate an odorant composition that is a mixture of those odorants. In addition, the disclosure of commercial sources (i.e., IFF, etc.) provides information to allow a person practicing the claimed method to acquire the recited mixture of odorants or components of the odorant mixture from a commercial source.

Further, it is well within the skill in the art to readily ascertain whether the mixture of odorants achieves the required effect without undue experimentation by following Appellant's disclosure, including the working example and the methods for ascertaining effectiveness.

Appellant further directs attention to the disclosure and claims of Appellant's issued U.S. Patent No. 5,885,614 (see Appeal Brief at Tab K). The claims are directed to administering odorants *and mixtures of odorants* to a male individual to increase penile blood flow. Similar to the present disclosure, the description in USP 5,885,614 provides an identification of a commercial source (IFF) for odorants (at col. 2, lines 40-42), and a working example of the use of various odorants and odorant mixtures. The allowed claims of USP 5,885,614 are similar to the presently pending claims in reciting the administration of mixtures of odorant. See, for example, Claim 1 (emphasis added):

USP 5,885,614: 1. A method of increasing penile blood flow in a male individual, comprising: administering to the male by inhalation of an odorant in an amount effective to increase penile blood flow; the odorant selected from the group consisting of...*a mixture of lavender and pumpkin pie, a mixture of doughnut and black licorice, a mixture of pumpkin pie and doughnut lily of the valley...a mixture of doughnut and cola, a mixture of black licorice and cola, a mixture of lavender and doughnut...*

USP 5,885,614 is further evidence that Appellant's disclosure and the presently pending claims are fully enabling to allow one skilled in the art to practice Appellant's method as claimed.

Appellant has provided a sufficiently supporting disclosure, both through the working example and descriptive discussion, to teach those of ordinary skill in the art how to make and use the invention as broadly as it is claimed and with the use of noncommercial or other commercial sources of the recited odorants, and to show that the claimed odorant mixtures are useful in altering blood flow to the vagina of a female individual.

Regarding the Examiner's Answer at pages 8-9 (bridging paragraph), Appellant has responded to the Examiner's assertion that the claims should be limited to the commercially identified odorants based on unpredictability between females. (See Appeal Brief at page 7-9.)

However, in the Examiner's Answer at pages 8-9, the Examiner *newly argues* that:

...the nature of the claimed/disclosed invention can be considered to be a female Viagra™ (i.e., those odorants which are disclosed as causing an increase in blood flow to the vagina) since Viagra™ is used to increase blood flow to the penis of a male and there have been countless unsuccessful attempts over the centuries to devise various types of female sexual arousal formulations.

The Examiner has provided no reference or other evidence in support of his unsubstantiated assertion of "countless unsuccessful attempts" to devise female sexual arousal formulations.

Furthermore, in the Office Action mailed January 3, 2002, the Examiner acknowledged that Appellant's Declaration (submitted in the Response filed July 2, 2001) demonstrated the success and effectiveness of his inventive method in altering blood flow to the vagina.<sup>1</sup>

The Examiner's unsupported assertion *should be given no weight* for requiring the claims to be limited to specific commercial embodiments.

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<sup>1</sup> See Office Action mailed January 3, 2002 (Paper No. 23) at page 4: "Based upon Applicant's response and Declaration of July 6, 2001, it is deemed that Applicant has reasonably demonstrated that the particular commercial odorants...act to alter blood flow to the vagina via inhaling an effective amount thereof."

In the Examiner's Answer at page 9 (first full parag.), the Examiner addresses the Doty publication (See Appeal Brief at Tab C). As admitted by the Examiner, Doty describes a test for identifying odorants (the "Smell Identification Test™). According to the test, a male or female subject inhales an odorant and then attempts to identify it. Doty describes (at page 3) conducting five initial experiments to develop the Smell Identification Test™:

- Exp. 1: selection of stimuli;
- Exp. 2: examination of influence of variables such as the age, gender, and ethnic background of subjects on the scores of the developed Smell Identification Test™;
- Exp. 3: use of the test to discriminate among person with olfactory disorders;
- Exp. 4: determining test-retest reliability; and
- Exp. 5: comparison of test scores to results from a traditional detection threshold procedure.

In the Examiner's Answer at page 9, the Examiner states (emphasis added):

...although the Doty et al. reference is mainly directed to tests for identifying odorants, the overall teachings of Doty et al. show that, in general, these variables play a role in the ability of a person to perceive a given odor (and also that women and men perceive odors differently with regard to intensity, pleasantness, coolness/warmth, irritation, and familiarity – see, e.g., page 4 of Doty et al). Accordingly, *it would not be reasonable for one of skill in the art to wholly dissociate such variables in the smell perception of an odor from the physiological effect(s) the perceived odor has upon an individual, including a female individual.*

Doty at pages 3-4 is reporting on Experiment 1, which was conducted to select appropriate stimuli (odorants) for the development of the Smell Identification Test™. Doty at page 4 describes the administration of 50 microencapsulated odorants to fifty men and women to rate the odorants on intensity, pleasantness, coolness/warmth, irritation and familiarity. Doty states the results as follows (emphasis added):

In general, the results indicated that...(c) *women* rated the odors, on the average, as slightly more intense, more unpleasant, less cool, less irritating, ***and more familiar than did men***...Despite the fact that there was a significant tendency for the familiarity ratings to *differ between the sexes* as a function of the odorants evaluated, the stimuli rated as more familiar by men than by women did not differ in any obvious way from the other odorants.

Doty provides no information relating to the physiological effect of odor stimulants. Doty merely addresses the ability of women as a group to identify odorants and odor characteristics as compared to men as a group. The differences in the ability between men and women to identify an odorant, which was examined by Doty, does not indicate any varying physiological effect of odorants between female individuals — particularly with regard to

administering an odorant mixture *to a female individual* to alter blood flow to the vagina of the female individual, as presently claimed.

The Examiner has made an interpretation of Doty's disclosure that is clearly unsupported by that reference, and *should be given no weight*.

Doty's disclosure does not indicate that odorant mixtures incorporating non-commercial or other commercial sources of odorants would be highly unpredictable between females in its effect in altering blood flow to the vagina, and does not provide a basis for requiring the claims to be limited to specific commercial embodiments.

The Examiner has made a determination of non-enablement based on conclusory statements without persuasive reasons or adequate support, and has failed to weigh all of the evidence before him. Appellant has demonstrated that the disclosure as filed would have enabled Appellant's methods as claimed for one skilled in the art at the time of filing. The Examiner has failed to consider Appellant's specification including the experimental example providing guidance, what was well known to one of skill in the art, and the high level of skill of those in the odorant arts.

The Examiner has provided no persuasive reason why the specification does not realistically enable one skilled in the art to practice the invention as broadly as claimed through the use of noncommercial or other commercial sources of the recited odorants. *In re Bowen*, 181 USPQ 48, 51 (CCPA 1974).

Appellant believes that the present disclosure is fully enabling for the claims as written, and for non-commercial and other commercial sources of odorants, and requests that the Examiner withdraw the rejection.

**B. Rejection under 35 U.S.C. § 112(2).**

Finally, in response to the Examiner's Answer at pages 9-10, which addresses Appellant's arguments on the rejection of claims for indefinite claim language under 35 U.S.C. § 112(2), the Examiner has not fully considered Appellant's arguments and supporting evidence.

First, in response to the Examiner's referral to "*odorants having the unusual functional effects upon females as instantly disclosed/claimed*,"<sup>2</sup> this is no basis for a rejection of the claims as indefinite or for requiring that the claims are limited to specific commercial embodiments of odorants.

The Examiner acknowledged the Declaration submitted in the present application in response to the Examiner's rejection of lack of utility and non-enablement in which he challenged the believability of Appellant's method and the data provided in Appellant's experimental examples.<sup>3</sup> The results of Appellant's experimental examples, shown in Tables I-V, fully support Appellant's finding that odorants can be administered to a female individual to alter blood flow to the vagina. (Specification at pages 12-15.)

The unusual effect provided by Appellant's method and the articles as presently claimed is evidence of the non-obviousness of those claims. It does not support a finding of either indefinite claim language or non-enablement.

Second, the claims on appeal employ language known and used in the art and which is of the same scope as the described invention. The language of the claims adequately defines the metes and bounds of the claimed invention.

Appellant has submitted various patents and documentation to show the acceptance in the art of the terms "chocolate odorant", etc., as well as the use and construction applied to these terms by the USPTO. Such use demonstrates the acceptance and an understanding of these terms in the art, as well as the construction applied to these terms and understanding of other Examiners in the USPTO.

The terms licorice, cucumber, lavender, pumpkin pie, baby powder, and chocolate odorants have been utilized in various contexts including Applicant's own issued patents as well as other issued patents and publications — *including the cited Doty publication* (see at page 7 listing licorice, chocolate, pumpkin pie odorants), for example.

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<sup>2</sup> See last sentence on page 10 of the Examiner's Answer. This statement is also repeated numerous times under the Grounds of Rejection at pages 4-5 of the Examiner's Answer.

<sup>3</sup> See footnote 1.

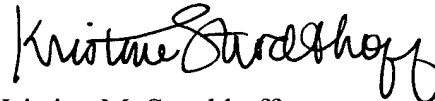
As such, the Examiner's interpretation of the claims is overbroad in view of how the term is used and understood by one skilled in the art and conflicts with the meaning give to identical terms in other patents from analogous art.

One skilled in the odorant arts reading the claims would readily understand the metes and bounds of those terms in the claims when read in light of the specification, which sets forth examples for such odorants, and in view of the knowledge in the art, as evidenced by Applicant's issued patents and Doty's publication, among others. It is respectfully submitted that the nature and identity of the recited odorants is not ambiguous to one skilled in the odorants arts.

### REQUEST

For the reasons stated above, and the reasons presented in Appellant's Brief on Appeal, Appellant believes that the claims on appeal fully comply with the requirement of 35 U.S.C. § 112, and earnestly requests that the final rejection of the claims on appeal be reversed.

Respectfully submitted,



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Dated: March 13, 2003

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